

**Express Mail No.: EJ 77936305US**

### REMARKS

Claims 1, 3-6, 8-12, 18-26, 28-37, and 39-40 are pending in the application. Claims 1-12 and 18-40 stand rejected. Claims 2, 7, 13-17, 27, and 38 have been canceled.

In accordance with 37 C.F.R. 1.136(a), a three month extension of time is submitted herewith to extend the due date of the response to the Office Action dated June 6, 2003, for the above-identified patent application from September 6, 2003, through and including December 6, 2003. In accordance with 37 C.F.R. 1.17(a)(3), authorization to charge a deposit account in the amount of \$950.00 to cover this extension of time request also is submitted herewith.

The rejection of Claims 1, 6-12, 18-26, 28-37, and 39-40 under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Claims 1, 26, and 34 have been amended and Claim 7 has been canceled. For the reasons set forth above, Claims 1, 6-12, 18-26, 28-37, and 39-40 are submitted to overcome the Section 112, First Paragraph rejections. Accordingly, Applicant respectfully requests that the Section 112 rejections of Claims 1, 6-12, 18-26, 28-37, and 39-40 be withdrawn.

The rejection of Claims 1-12, 18-26, 28-37, and 39-40 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. Claims 1, 26, and 34 have been amended and Claims 2 and 7 have been canceled. For the reasons set forth above, Claims 1-12, 18-26, 28-37, and 39-40 are submitted to overcome the Section 112, Second Paragraph rejections. Accordingly, Applicant respectfully requests that the Section 112 rejections of Claims 1-12, 18-26, 28-37, and 39-40 be withdrawn.

The rejection of Claims 1-5, 7-12 and 23-40 under 35 U.S.C. § 103 as being unpatentable over Baggiolini et al. (US Patent No. 5,087,619) and Abdaimi et al. (Cancer Research, 1999, 59:3325-3328) is respectfully traversed.

Claim 1 recites a "method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-}23\text{-yne-D}_3$  and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-}24,26,27\text{-trihomo-D}_3$  and stereoisomers thereof."

**Express Mail No.: E177936305US**

Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal comprising administering an effective amount of a Vitamin D analog. Baggiolini et al. fail to teach or suggest a method as recited in Claim 1.

Abdaimi et al. teach the use of EB 1089 as an antiproliferative and prodifferentiative agent. Abdaimi et al. do not teach nor suggest a dog food comprising a proteinaceous component, a farinaceous component and a therapeutic agent comprising a vitamin D analog.

Applicant respectfully submits that Baggiolini et al. and Abdaimi et al. do not teach nor suggest the method recited in Claim 1. Neither Baggiolini et al. nor Abdaimi et al. teach or suggest a method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$  and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof. Specifically, neither Baggiolini et al. nor Abdaimi et al. teach or suggest feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$  and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof. For the reasons set forth above, Applicant submits that Claim 1 is patentable over Baggiolini et al. and Abdaimi et al.

Claims 2 and 7 have been canceled. Claims 3-5, 8-12, and 23-25 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 3-5, 8-12 and 23-25 are considered in combination with the recitations of Claim 1, Applicant submits that dependent Claims 3-5, 8-12 and 23-25 likewise are patentable.

Claim 26 recites a method of "providing a therapeutic agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$ , and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof, said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet."

Applicant respectfully submits that Baggiolini et al. and Abdaimi et al. do not teach nor suggest the method recited in Claim 26. Neither Baggiolini et al. nor Abdaimi et al.

**Express Mail No.: EL7936305US**

teach or suggest a method of providing a therapeutic agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$ , and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof, and said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet."

Specifically, neither Baggiolini et al. nor Abdaimi et al. teach or suggest providing a pet food to a pet including a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog, and feeding the pet food to a pet. For the reasons set forth above, Applicant submits that Claim 26 is patentable over Baggiolini et al. and Abdaimi et al.

Claim 27 has been canceled. Claims 28-33 depend from independent Claim 26. When the recitations of Claims 28-33 are considered in combination with the recitations of Claim 26, Applicant submits that dependent Claims 28-33 likewise are patentable.

Claim 34 recites a method of "administering a pharmaceutical agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$ , and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof, said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet."

Applicant respectfully submits that Baggiolini et al. and Abdaimi et al. do not teach nor suggest the method recited in Claim 34. Neither Baggiolini et al. nor Abdaimi et al. teach or suggest a method of administering a pharmaceutical agent to a pet, wherein the agent comprises a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne-D}_3$ , and  $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$  and stereoisomers thereof, said method comprising providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet.

Specifically, neither Baggiolini et al. nor Abdaimi et al. teach or suggest administering a pharmaceutical agent to a pet, wherein the agent comprises a vitamin D analog and the method comprises providing a pet food including a proteinaceous component, a farinaceous component, and the agent, and feeding the pet food to a pet. For the reasons set

**Express Mail No.: EJ 77936305US**

forth above, Applicant submits that Claim 26 is patentable over Baggiolini et al. and Abdaimi et al.

Claim 38 has been canceled. Claims 35-37 and 39-40 depend, directly or indirectly, from independent Claim 34. When the recitations of Claims 35-37 and 39-40 are considered in combination with the recitations of Claim 34, Applicant submits that dependent Claims 35-37 and 39-40 likewise are patentable.

The Examiner's combination of Baggiolini et al. with Abdaimi et al. is traversed since there is no teaching nor suggestion in either Baggiolini et al. nor Abdaimi et al. for the combination.

Applicant respectfully submits that the Examiner's Section 103 rejection of Claims 1-5, 7-12 and 23-40 is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al. according to the teachings of Abdaimi et al.

More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. The required teaching, suggestion and incentive supporting the Examiner's combination is absent here. Neither Baggiolini et al. nor Abdaimi et al. teach or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicant respectfully submits that it would not be obvious to one skilled in the art to combine Baggiolini et al. with Abdaimi et al. because there is no motivation to combine these references suggested in the art. The Examiner has not pointed to any prior art that teaches or suggests combining the disclosures.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicant's disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicant's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion nor motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown. Specifically, the Examiner has not pointed to any prior art that teaches or suggests a reasonable expectation of success or motivation in combining the references.

**Express Mail No.: EJ 77936305US**

Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejection is apparently based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention.

Since there is no teaching, suggestion, or motivation in the cited references for the claimed combination recited in Claims 1-5, 7-12 and 23-40, the Section 103 rejection of Claims 1-5, 7-12 and 23-40 appears to be based on an impermissible hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible.

For at least the reasons set forth above, Applicant respectfully requests that the Section 103 rejections of Claims 1-5, 7-12 and 23-40 is overcome and should be withdrawn.

The rejection of Claims 6 and 18-22 as being unpatentable under 35 U.S.C. § 103 over Baggiolini et al. and Abdaimi et al. as applied to Claims 1-5 and 7-12 and in view of Katzung (Basic and Clinical Pharmacology, p.661-663, 838, 841, 830-832) and Hardman et al. (Goodman and Gilman's The Pharmacological Basis of Therapeutics, P. 539) is respectfully traversed.

Claims 6 and 18-22 depend from Claim 1. Baggiolini et al. and Abdaimi et al. are described above. Katzung teaches that hypercalcemia causes central nervous system depression, including coma and is potentially lethal. Its major causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases. Further Katzung teaches that less common causes are hypervitaminosis D, sarcoidosis, thyrotoxicosis, mil-alkali syndrome, adrenal insufficiency and immobilizations. Hardman et al. is a page from a text book indicating that pain is associated with cancer.

Claim 1 recites a "method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a

**Express Mail No.: EJ 77936305US**

vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2$ -16-ene-23-yne- $\text{D}_3$  and  $1\alpha,25-(\text{OH})_2$ -22,24-diene-24,26,27-trihomo- $\text{D}_3$  and stereoisomers thereof."

Applicant respectfully submits that none of Baggiolini et al., Abdaimi et al., Katzung and Hardman et al. teach or suggest a method as recited in Claim 1. Specifically, none of Baggiolini et al., Abdaimi et al., Katzung, and Hardman et al. teach or suggest feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog selected from the group consisting of  $1\alpha,25-(\text{OH})_2\text{D}_3$ ,  $1\alpha,25-(\text{OH})_2$ -16-ene-23-yne- $\text{D}_3$  and  $1\alpha,25-(\text{OH})_2$ -22,24-diene-24,26,27-trihomo- $\text{D}_3$  and stereoisomers thereof. Rather, Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal comprising administering an effective amount of a Vitamin D analog; Abdaimi et al. teach the use of EB 1089 as an antiproliferative and prodifferentiative agent; Katzung teaches that hypercalcemia causes central nervous system depression, including coma and is potentially lethal. Its major causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases; and Hardman et al. is a page from a text book indicating that pain is associated with cancer. For the reasons set forth above, Applicant submits that Claim 1 is patentable over Baggiolini et al., Abdaimi et al., Katzung, and Hardman et al.

In addition, Katzung appears to be a non-analogous reference since Katzung does not relate to a method of treating SCC 2/88, a canine squamous carcinoma cell line, for cancer, comprising the step of feeding a dog a dog food comprising a proteinaceous component, a farinaceous component, and a therapeutic agent comprising a vitamin D analog, as recited in Claim 1. Accordingly, Claim 1 is submitted to be patentable over Baggiolini et al. and Abdaimi et al. in view of Katzung and Hardman et al.

When the recitations of Claims 6 and 18-22 are considered in combination with the recitations of Claim 1, Applicant submits that dependent Claims 6 and 18-22 likewise are patentable.

Applicants respectfully submit that the Examiner's Section 103 rejection of the presently pending Claims 6 and 18-22 is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al. and Abdaimi et al. according to the teachings of Katzung and Hardman et al. More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention,

**Express Mail No.: EI 77936305US**

absent some teaching, suggestion, or incentive supporting the combination. The required teaching, suggestion and incentive supporting a combination is absent here. None of Baggiolini et al., Abdaimi et al., Katzung and Hardman et al. teach or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicant respectfully submits that it would not be obvious to one skilled in the art to combine Baggiolini et al., Abdaimi et al., Katzung, and Hardman et al. because there is no motivation to combine the references suggested in the art. The Examiner has not pointed to any prior art that teaches or suggests combining these pieces of prior art.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicant's disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicant's disclosure. In re Vaack, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown. Specifically, the Examiner has not pointed to any prior art that teaches or suggests a reasonable expectation of success or motivation in combining the references.

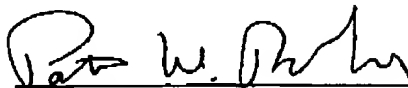
Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejection is apparently based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention.

Since there is no teaching, suggestion, or motivation in the cited references for the combination recited in Claims 6 and 18-22, the rejection of Claims 6 and 18-22 appears to be based on impermissible hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason, Applicant requests that the 35 USC § 103 rejection of Claims 6 and 18-22 be withdrawn.

**Express Mail No.: EI 77936305US**

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully submitted,



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